RESPONSE TO AMENDMENT

The amendment filed 4/8/2008 has been entered into the record. Claims 2,3,5 and 37-42 have been cancelled. New claims 43-45 have been added. Claims 6-16, 18-21 and 25-36 were previously not treated on the merits due to improper multiple dependency. Applicants have now amended claims 6-16, 18-21 and 25-36 to place the claims in proper dependency and so the claims are now under examination.

Claims 1,4,6,7-36 and 43-45 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Objections Withdrawn

The objection to claims 6-16, 18-21 and 25-36 is withdrawn.

The objection to claims 1 and 3 is withdrawn.

Claim Objections

Claims 25,27,30,31 and 34 are objected to for being improper dependent form. A claim cannot depend from a later claim.

Claims 4, 6, 7-36 and 43-45 are objected to due to the following minor informality: 'claim' should be all small letters i.e. instead of 'Claim'.

Appropriate correction is required.

Rejections Withdrawn

The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

The rejection of claims 37-42 rejected under 35 U.S.C. 112, first paragraph is withdrawn in view of the cancellation of the claims.

The rejection of claims 17 and 22-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

The rejection of claims 37 and 40 under 35 U.S.C. 102(b) as being clearly by anticipated by Simon, Benjamin. Dissertation Abstracts International, 2002, vol. 62/10-B, p. 4363 as evidenced by both Morzunov et al. Virus Research. 1995 Oct. Vol. 38:175-192 and Argenton et al, Diseases of Aquatic Organisms, vol. 24:121-127, 1996 is withdrawn in view of the cancellation of the claims.

The rejection of claims 38, 39,40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon, Benjamin. Dissertation Abstracts International,2002, vol. 62/10-B, p.

4363 as applied to claim 37 and 40 above in view of Gudding et al. Veterinary Immunology and Immunopathology, 72 (1999): 203-212 is withdrawn in view of the cancellation of the claims.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-36 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for protecting fish from salmonid rickettsial septicemia and infectious pancreatic necrosis (IPN) comprising administering to fish a composition comprising the p45 antigen and IPN antigens of VP2 and VP3 protein, does not reasonably provide enablement for a method for protecting fish from IPN comprising administering said p45 antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention is drawn to a method of protecting a fish from both salmonid rickettsial septicemia (SRS) and infectious pancreatic necrosis (IPN) by administering to fish a vaccine comprising 1) an isolated p45 protein; or (2) the nucleic acid encoding the p45 protein, or (3) a recombinant *Yersina ruckeri* cell comprising an expression vector comprising the nucleic acid that encodes p45 protein.

The specification teaches that the p45 protein is obtained from the bacterium *Piscirickettsia salmonis* (see background p. 1-3 of the specification). The specification discusses other antigens obtained from other infectious agents infecting fish such as the VP2 and VP3 protein of the infectious pancreatic necrosis (IPN) virus. The specification teaches that a composition comprising both the bacterin of Yersinia ruckeri carrying the p45 antigen and said IPN antigens are administered to Atlantic salmon and said composition is efficacious and provides for a reduction in mortality (93.6% survival when control group is at 60% mortality and 30% survival when control group is at 94% survival) when said salmon is challenged with *P. salmonis*. See example 8 p. 86-89. The specification also teaches a composition comprising only the bacterin of *Yersinia ruckeri* carrying the p45 antigen which also provides for a reduction in mortality (100% survival when control group is at 60% mortality and 43% survival when control group is at 94% survival). See example 7 especially p.84.

While the specification has provided for protection against SRS using the p45 antigen, the specification does not provide for protection from IPN using the p45 antigen alone as claimed. The specification does not teach that the p45 antigen is an antigen of IPN virus and the specification does not teach any protective epitopes that might be present in the p45 antigen that will also protect fish from IPN. The specification does not provide for any efficacy data that

demonstrates that the instant p45 antigen of *P. salmonis* protects fish from IPN. The specification does not correlate any immunogenic response obtained by administering any of the p45 antigen numbered 1-3 above with protective efficacy against infectious pancreatic necrosis in any fish. Without any identification of cross-protective epitopes in p45 that protects from IPN, it is unpredictable that a *P. salmonis* antigen (protein or nucleic acid) would protect against a disease caused by infectious pancreatic necrosis virus. Thus, for the reasons above, undue experimentation would be required of the skilled artisan to use the full scope of the invention as claimed in claims 34-36 and 44.

Claims 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the *Pichia pastoris* cells with accession No. IHEM 20069 and IHEM 20071. Because it is not clear that said cells with the properties of IHEM 20069 and IHEM 20071are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims requires IHEM 20069 and IHEM 20071, a suitable deposit for patent purposes is required. Exact replication of each of the yeast cells is an unpredictable event.

Applicant's referral to the deposit of said yeast on page 16 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR §1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, *that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required.* This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;

4) The identity of the deposit and the accession number given by the depository;

5) The date of the viability test;

6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Applicant's attention is directed to *In re Lundack*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8 and 43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a nucleic acid that hybridizes to the nucleotide sequence of claim 7; and wherein said nucleic acid comprises at least 12 nucleotides; and the nucleic acid of claim 8 that hybridizes to the nucleotide sequence of claim 7 under stringent conditions wherein the Tm is 65oC.

Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. The recitation of isolated or purified to distinguish the instant nucleic acids and proteins from that found in nature will obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs Catalog, 1996/1997 p. 111 – Random primers.

The claims are drawn to a nucleic acid that hybridizes to the nucleotide sequence of claim 7; and wherein said nucleic acid comprises at least 12 nucleotides and the nucleic acid of claim 8 that hybridizes to the nucleotide sequence of claim 7 under stringent conditions wherein the Tm is 65oC.

New England catalog teaches random primers consisting of every possible combination of any 12 nucleotides or any 24 nucleotides or any 36 nucleotides. Thus, New England Biolabs teaches a nucleic acid that hybridizes to at least 12 nucleotides of the nucleotide sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 3 and said nucleic acid will hybridize under stringent conditions wherein the Tm is 65oC, absent evidence to the contrary.

Status of Claims

Claims 8, 28, 29, 34-36, 43 and 44 are rejected. Claims 4, 6, 7-36 and 43-45 are objected to due to informalities. Claim 1 is allowable.

Applicant's amendment to claims 6-16, 18-21 and 25-36 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645